IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

IN RE: AREDIA AND ZOMETA PRODUCTS LIABILITY LITIGATION	) NO. 3:06-md-1760) JUDGE CAMPBELL
This Document Relates to Case No. 3:08-00071 (Deutsch)	)

MEMORANDUM

Pending before the Court is Defendant's Motion for Summary Judgment (Docket No. 2297). For the reasons stated herein, Defendant's Motion is GRANTED in part and DENIED in part. Plaintiff's claim for breach of express warranty is DISMISSED.

FACTS

Plaintiff Deutsch brings this action against Novartis alleging that Novartis' drugs, Aredia and Zometa, caused his deceased wife to develop osteonecrosis of the jaw ("ONJ"). Plaintiff alleges causes of action for (1) strict liability, (2) negligent manufacture, (3) negligent failure to warn, (4) breach of express warranty, (5) breach of implied warranty, and (6) loss of consortium. Defendant has moved for summary judgment on all claims.

SUMMARY JUDGMENT

Summary judgment "should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). In deciding a motion for summary judgment, the Court must review all the evidence, facts and inferences in the light most favorable to the nonmoving party. *Van Gorder v. Grand Trunk Western Railroad, Inc.*, 509 F.3d 265, 268 (6th Cir. 2007). In order to defeat a summary judgment motion, the nonmoving

party must provide more than a scintilla of evidence; that is, the nonmoving party must present evidence sufficient to permit a reasonable jury to find in its favor. *Van Gorder*, 509 F.3d at 268. Entry of summary judgment is appropriate against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's cases, and on which that party will bear the burden of proof at trial. *Id*.

CAUSATION

Under New York law, which must be applied in this case, the plaintiff must tender evidence in an admissible form demonstrating both general causation and specific causation in a failure to warn products liability case. *Heckstall v. Pincus*, 797 N.Y.S.2d 445, 447 (N.Y. App. Div. 2005). Defendant first contends that Plaintiff's claims must fail because he cannot establish general causation, a required element of all his claims. Defendant bases this argument on its Motion for Summary Judgment Based upon a Failure of General Causation Proof under *Daubert*. The Court has denied that motion and found that there are genuine issues of material fact as to whether Zometa and Aredia generally can cause ONJ.

Next, Defendant argues that Plaintiff cannot prove specific causation; that is, that Zometa proximately caused Mrs. Deutsch's ONJ. Defendant has moved to exclude Plaintiff's non-retained specific causation experts, and the Court has not considered the causation testimony of those witnesses. Plaintiff has offered the opinion of a retained expert, Dr. Najjar, however, to testify about specific causation. For purposes of summary judgment, the Court has denied Defendant's motion to exclude the testimony of Dr. Najjar under *Daubert*.

Dr. Najjar's expert opinion is admissible for purposes of summary judgment, and Dr. Najjar has stated in his report: "I am convinced with reasonable medical certainty that Mrs. Deutsch suffers

from bisphosphonate osteonecrosis of the jaw ("BONJ") due to her treatment with Aredia for over four years and Zometa for less than two years." Najjar Report (Ex. 4 to Docket No. 2505).

Dr. Najjar's discussion of other potential risk factors for ONJ does not change his opinion that Mrs. Deutsch had BONJ. Defendant's attacks on Dr. Najjar's opinion go to the credibility and accuracy of that opinion, but for purposes of summary judgment, Plaintiff has carried his burden. Defendant's motion on this issue is denied.

FAILURE TO WARN
(STRICT LIABILITY AND NEGLIGENCE)

Regardless of the descriptive terminology used to denominate the cause of action, where the theory of liability is failure to warn, negligence and strict liability are equivalent under New York law. *Wolfgruber v. Upjohn Co.*, 423 N.Y.S.2d 95, 97 (N.Y. App. Div. 1979). Whether an action is pleaded in strict products liability, breach of warranty or negligence, it is the plaintiff's burden to show that a defect in the product was a substantial factor in causing the injury and that the defect complained of existed at the time the product left the manufacturer. *Tardella v. RJR Nabisco, Inc.*, 576 N.Y.S.2d 965, 966 (N.Y. App. Div. 1991).

To succeed on a failure to warn claim, plaintiffs are required to prove that the product did not contain adequate warning and that the inadequacy of the warnings was the proximate cause of the injury. *Mulhall v. Hannafin*, 841 N.Y.2d 282, 285 (N.Y. App. Div. 2007). The manufacturer's duty, under New York law, is to warn the medical community, not the patient, of the product's risk. *Id.*[1]

[1] Under this "informed intermediary doctrine," the manufacturer of a prescription drug has a duty to warn of all potential dangers which it knows or should know and must take such steps as are reasonably necessary to bring that knowledge to the attention of the medical profession. *Figueroa v. Boston Scientific Corp.*, 254 F.Supp.2d 361, 370 (S.D. N.Y. 2003).

Defendant argues that its warnings were adequate, for the reasons stated in its Motion for Summary Judgment on the Adequacy of its Aredia and Zometa Warnings. The Court has found that there are genuine issues of material fact as to the adequacy of Defendant's warnings and denied that Motion. "Generally, whether a warning is adequate is an issue of fact to be determined at trial." *Figueroa v. Boston Scientific Corp.*, 254 F.Supp.2d 361, 370 (S.D. N.Y. 2003).

To establish his failure to warn claim, Plaintiff also has the burden to show that had a different warning been given, Mrs. Deutsch would not have used the product that caused her injury. *Mulhall*, 841 N.Y.S.2d at 287. The *Mulhall* court stated that, in that case, the plaintiff had to show that, had the warning been different, the doctor would have departed from her normal practice and used another product. *Id*.[2]

It remains Plaintiff's burden to prove that Defendant's failure to warn was a proximate cause of the injury, and this burden includes adducing proof that the user of a product would have read and heeded a warning had one been given. *Sosna v. American Home Products*, 748 N.Y.S.2d 548, 549 (N.Y. App. Div. 2002). To constitute proximate cause, an inadequate warning must be a substantial cause of the events leading to the injury. *Figueroa*, 254 F.Supp.2d at 370. Plaintiffs need not positively exclude every other possible cause; rather, the proof must render those other causes sufficiently remote or technical to enable a jury to reach its verdict based not upon speculation, but

[2] In *Mulhall*, which involved a medical device, the doctor had testified that she selected the product over all other available devices because she had used it safely in her practice since 1992 and the medical literature had documented that it performed well without side effects. *Mulhall*, 841 N.Y.S.2d at 287.

upon the logical inferences to be drawn from the evidence. *Gayle v. City of New York*, 703 N.E.2d 758, 759 (N.Y. 1998).[3]

Mrs. Deutsch's oncologist stopped her prescription of Zometa when she developed ONJ. Kappel Deposition (Docket No. 2514-5), pp. 30, 144 and 156. He has changed his prescribing habits based upon additional information about ONJ occurring in patients taking Zometa. *Id*., p. 124. He is now "much more concerned about dental care prior to the beginning or at the first sign of any kind of dental complaint, having the patient evaluated." *Id*. Dr. Kappel testified that if he has a patient now who is going for an extraction of the tooth, "they are not getting Zometa or Aredia." *Id*. at 165. And, "that's different from what I would have said in 2002." *Id*. Mrs. Deutsch testified that she would not have taken Aredia or Zometa if she had been warned of the potential risks of ONJ. Deutsch Deposition (Docket No. 2514-1), pp. 368-71.

Dr. Molinari, Mrs. Deutsch's dentist, testified that now, in the presence of bisphosphonates, ONJ is treated differently. Molinari Deposition (Docket No. 2514-4), p. 176. He stated that "now we look at it as total conservative treatment; rather than before, when we didn't know, we were able to do more invasive procedures." *Id*. He testified that with a severely broken down tooth, "where

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[3] In *Hoffman-Rattet v. Ortho Pharmaceutical Corp.*, 516 N.Y.S. 2d 856 (N.Y. Sup. Ct. 1987), the court held that, once a patient establishes that an inadequate warning has been given, a presumption arises that the inadequacy was a proximate cause of the pharmaceutical item in question having been prescribed or continued. *Id.* at 861. This presumption may then be rebutted by affirmative evidence introduced by the defendant showing that even if adequately informed, the physician would still have prescribed the item. *Id*.; *see also Anderson v. Hedstrom Corp.*, 76 F.Supp.2d 422, 441 (S.D. N.Y. 1999). In this case, however, the Court has found that, for purposes of summary judgment, there are questions of fact as to the adequacy of Defendant's warnings, so the burden has not shifted to Defendant.

before we will extract it, now we will do the root canal . . . rather than going ahead and extracting the tooth." *Id*. at 177.

Plaintiff has sufficiently established genuine issues of material fact as to whether different warnings would have made a difference in the behavior of his wife or her treating physicians; that is, whether Defendant's failure to warn was a proximate cause of Mrs. Deutsch's injury. Defendant's Motion for Summary Judgment on this issue is denied.

EXPRESS WARRANTY

An express warranty, under New York law, is an "affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain." *Horowitz v. Stryker Corp.*, 613 F.Supp.2d 271, 286 (E.D. N.Y. 2009). An action for breach of express warranty requires both the existence of an express promise or representation and reliance on that promise or representation. *Id*.

Plaintiff's only response to Defendant's arguments concerning the breach of express warranty claim is his allegation that a handout received from Defendant by Dr. Kappel (and given by him to his patients) did not include information about ONJ or BONJ. Plaintiff also asserts that information on that handout regarding adverse reactions and overdosage constituted an express warranty. The Court disagrees. The alleged information (or lack thereof) does not constitute an affirmation or promise; neither is there evidence that it became part of the basis of the bargain upon which either the physicians or Mrs. Deutsch relied in purchasing Defendant's products.

Therefore, Defendant's Motion for Summary Judgment on Plaintiff's breach of express warranty claim is granted, and that claim is dismissed.

IMPLIED WARRANTY

Plaintiff's breach of implied warranty claim is also based upon the alleged failure to warn. Thus, as with the strict liability and negligent failure to warn claims, there are genuine issues of material fact which preclude summary judgment on the breach of implied warranty claim as well. Therefore, Defendant's Motion for Summary Judgment on this claim is denied.

LOSS OF CONSORTIUM

Plaintiff's loss of consortium claim derives from and is dependent upon Plaintiff's other claims. Therefore, Defendant's Motion for Summary Judgment on this claim is denied.

IT IS SO ORDERED.

Todd Campbell

TODD J. CAMPBELL
UNITED STATES DISTRICT JUDGE